IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,	)	
	)	
Plaintiff and	)	
Counterclaim Defendant,	)	
	)	
v.	)	02: 02cv1628
	)	
MYLAN LABORATORIES, INC. and	)	
MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendants and	)	
Counterclaim Plaintiffs.	)	

MEMORANDUM OPINION AND ORDER OF COURT

November 17, 2006

Presently before the Court are two Motions to Preclude Expert Testimony. Plaintiff and Counterclaim-Defendant Pfizer Inc. ("Pfizer") filed a MOTION IN LIMINE TO PRECLUDE THE TRIAL TESTIMONY OF KEVIN BURGESS Ph.D. Defendants and Counterclaim-Plaintiffs Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively referred to as "Mylan") filed a MOTION IN LIMINE TO STRIKE DR. ANDERSON'S EXPERT REPORT AND PRELUDE HIS TESTIMONY REGARDING UNRELIABLE METHODOLOGY. The issues have been fully briefed and replied and the matter is ripe for disposition.

After a careful consideration of the motions, the Court finds that there is no basis to exclude any of the proposed testimony being challenged. Therefore, these Motions will be denied for the following reasons.

BACKGROUND

The facts of the case have been amply set forth in the previous opinions rendered by the Court in this case.[1] Therefore, the Court will merely provide an abridged summary of facts for the purpose of this Opinion.

This is a patent infringement action brought by Pfizer, whose two patents cover an amlodipine besylate product sold under the trade name, Norvasc®: United States Patent No. 4,572,909 ("the '909 patent") and United States Patent No. 4,879,303 ("the '303 patent").[2] On May 22, 2002, Mylan filed an Abbreviated New Drug Application ("ANDA") in which it sought approval to sell generic amlodipine besylate. By letter dated July 23, 2002, Mylan certified pursuant to 21 C.F.R. 314.94(a)(12)(i)(A)(4) that it was seeking approval to market its generic copy of Norvasc® prior to the expiration of the '909 and '303 patents. The application stated that to the best of Mylan's knowledge neither the '909 nor the '303 patents would be infringed by the manufacture, use or sale of the proposed generic amlodipine besylate.

On September 20, 2002, Pfizer sued Mylan for infringement of both patents pursuant to 35 U.S.C. § 271(e)(2)(A).

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1 *See Memorandum Opinion and Order of Court* denying Motion for Partial Summary Judgment on Invalidity of Claims 1-11 of U.S. Patent No. 4,572,909 (Document No. 143) and *Sealed Memorandum Opinion and Order of Court* dated June 29, 2006, denying Motion for Summary Judgment Striking The Defense and Dismissing the Counterclaims Relating to Inequitable Conduct (Sealed Document No. 144).

2 The claims of the '909 patent cover a genus of compounds that includes amlodipine, and contains a specific claim (claim 8) to amlodipine. The '909 patent expired on July 31, 2006, and is no longer at issue in this suit.

On October 4, 2005, Mylan announced that it had received final approval from the FDA of its ANDA application. To date, however, Mylan has not begun to market the generic Mylan Amlodipine Tablets described in ANDA No. 76-418.

The '909 patent expired on July 31, 2006; the '303 patent will expire in March 2007. A non-jury trial is scheduled to commence in this matter on November 28, 2006.

STANDARD OF REVIEW

Rule 702 of the Federal Rules of Evidence governs the testimony of expert witnesses and provides that such testimony is permitted if it will "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). The requirements of Rule 702 "mandate[s] a policy of liberal admissibility." *Paoli,* 35 F.3d at 741. In other words, the role of a district court is to only exclude expert testimony that clearly does not meet the requirements of Rule 702.

Pursuant to Rule 702, the Court must first determine whether the witness is qualified by virtue of "specialized knowledge" regarding the area of the proposed testimony. "The basis of this specialized knowledge 'can be practical experience as well as academic training and credentials'." *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998). The United States Court of Appeals for the Third Circuit has interpreted the specialized knowledge requirement liberally. *Id*. It would be an abuse of the trial court's discretion to exclude testimony "simply because the

trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." *In re: Unisys Savings Plan Litigation*, 173 F.3d 145, 170 (3d Cir.), *cert. denied, Meinhardt v. Unisys Corp.*, 528 U.S. 950 (1999). However, "at a minimum, a proffered expert witness . . . must possess skill or knowledge greater than the average layman . . . ." *Waldorf*, 142 F.3d at 625 (*quoting Aloe Coal Co. v. Clark Equip. Co.,* 816 F.2d 110, 114 (3d Cir.), *cert. denied*, 484 U.S. 853 (1987). This does not mean that an expert must rely solely on his own work, but he can rely on another's information or work, if it is of the type normally relied upon by an expert in the course of his work. *United States v. Arias*, 678 F.2d 1202, 1206 (4th Cir.1982), *cert. denied*, 495 U.S. 910 (1982); *Polymer Dynamics, Inc. v. Bayer Corp.*, 2005 WL 1041197, at *2 (E.D. Pa. May. 4, 2005).

With regard to the second two factors, reliability and fit, the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), held that the district court is to act as a "gatekeeper" to evaluate whether an expert's testimony "rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. In assessing the "reliability" of the testimony, the factors to consider are: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subjected to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *Oddi*, 234 F.3d at 741 (*citing Paoli*, 35 F.3d at 742 n. 8). "The test of

admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather, the test is whether 'the particular opinion is based on valid reasoning and reliable methodology'." *Oddi*, 234 F.3d at 145-46 (*quoting Kannankeril v. Terminix Int'l Inc*., 128 F.3d 802, 806 (3d Cir. 1997)). In addition, even if the expert's methodology is found to be sufficient, to be admissible the testimony must also be found to assist the trier of fact. *Paoli*, 35 F.3d at 743. However, the district court should only determine if the expert testimony is sufficient to satisfy the requirements of Rule 702, not determine if the facts and assumptions of an expert are "overwhelming." *Stecyk v. Bell Helicopter Textron, Inc*., 295 F.3d 408, 414 (3d Cir. 2002) (holding "[a] party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination").

Discussion

A. Pfizer's Motion to Preclude The Trial Testimony of Kevin Burgess Ph.D.

Mylan seeks to offer Kevin Burgess, Ph.D., a synthetic organic chemist who will testify to a variety of issues, which include: (i) the "Michael Reaction," the cause of the prevalent impurity in amlodipine maleate; (ii) the teaching of the Michael Reaction in undergraduate organic chemistry courses; (iii) the fact that the Michael Reaction cannot occur in amlodipine besylate; (iv) the '303 patent applicants' knowledge that the Michael Reaction was the cause of the prevalent impurity in amlodipine besylate; (v) the '303 patent applicants' knowledge that the Michael Reaction would not occur in amlodipine besylate and that it expected the besylate to be more stable than the maleate; and (vi) the '303 patent applicants'

knowledge about ways to control the Michael Reaction in amlodipine maleate. Mylan contends that these opinions are related to Mylan's defenses and counterclaims that the '303 patent is invalid and unenforceable. Pfizer argues that although Dr. Burgess is a trained and practicing synthetic organic chemist, "[h]e is not equipped by either his formal education or his research or teaching activities to provide expert opinions regarding what a formulation scientist of ordinary skill would expect regarding formulation stability of a new chemical salt or how that formulation scientist experimentally would have evaluated the salt's formulation properties."

The Court finds and rules that Dr. Burgess, while perhaps not a formulation scientist, has provided the necessary support to establish that he is qualified to testify as an expert in this matter. He holds a Bachelor of Science degree, a Masters degree in Physical Organic Chemistry, and a Ph.D. in Organometallic Chemistry. Dr. Burgess is a Professor at Texas A&M University and among the courses he teaches is undergraduate organic chemistry. Dr. Burgess has authored over 175 peer-reviewed publications, is named as an inventor on four United States patents, and has been an invited speaker at numerous universities and research facilities. Given that "a broad range of knowledge, skills, and training qualify an expert as such," and the liberal standards under Rule 702, the Court finds and rules that Dr. Burgess meets the first requirement of Rule 702. *Paoli II,* 35 F.3d at 741.

"The second requirement of Rule 702 - that the expert testify to . . .specialized knowledge - is intended to ensure the reliability or trustworthiness of the expert's testimony." *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995). Specialized knowledge has been defined as "skill or knowledge greater than the average layman." *Betterbox Communications, Ltd. v. BB Technologies, Inc.,* 300 F.3d 325, 328 (3d Cir. 2002). Most importantly, the

reliability requirement must not be applied "too strictly," since "[t]he ultimate touchstone of admissibility is helpfulness to the trier of fact." *Valasquez*, 64 F.3d at 850.

According to Mylan, Dr. Burgess will be testifying with respect to the "Michael Reaction." His testimony will include the mechanics of the Michael Reaction, the fact that the Michael Reaction was well known at the time that the patent application which matured into the '303 patent was filed, that people of skill in the art would have known that the maleate salt would be subject to the Michael Reaction while the besylate salt would not be, that the Pfizer scientists knew that the prevalent impurity detected in the maleate salt was the product of the Michael Reaction, and, that the Michael Reaction could be controlled by adjusting the reaction conditions.

Dr. Burgess bases his testimony regarding the Michael Reaction on scientific textbooks, his education, his teaching experience, and his review of Pfizer's documents.

The Court finds and rules that the topics of Dr. Burgess' planned trial testimony are clearly within his field of expertise and are "specialized" as required by Rule 702. Further, the Court finds and rules that the planned trial testimony of Dr. Burgess is "based on valid reasoning and reliable methodology." Accordingly, the Court finds and rules that Dr. Burgess' planned testimony is reliable and meets the second requirement of Rule 702.

The third, and final, requirement of "Rule 702 is to ensure that the evidence is relevant or 'fits' under the facts of the case." *Valasquez,* 64 F.3d at 850. Mylan contends that Dr. Burgess' testimony "is highly relevant to both the invalidity and unenforceability issues, and will be of assistance to the Court in evaluating the evidence on both issues." Br. at 9.

Our appellate court has instructed that "the helpfulness standard" should be "interpreted broadly." *American Technology Resources v. United States*, 893 F.2d 651, 655 (3d Cir. 1990). Accordingly, the Court finds and rules that the testimony of Dr. Burgess may assist the Court in determining whether (i) amlodipine besylate would be expected to be stable because it cannot undergo the Michael Reaction (an issue that goes to the validity of the '303 patent) and (ii) Pfizer knew the cause of the amlodipine maleate instability and how to control it (issues that go to the unenforceability of the '303 patent). Thus, the Court finds that the planned testimony of Dr. Burgess meets the third requirement of Rule 702.

For all these reasons, the motion to preclude the trial testimony of Dr. Burgess filed by Pfizer will be denied.

B. Mylan's Motion to Strike Dr. Anderson's Expert Report and Preclude His Testimony Regarding Unreliable Methodology

Pfizer seeks to offer Bradley R. Anderson, Ph.D, a pharmaceutical chemist who will testify about the summary (or ranking system) he prepared of the Pfizer laboratory records of numerous stability tests. Mylan argues that "the principles and methodology of Dr. Anderson's ranking system fail the test for reliability, and paragraphs 81-84 of his expert report regarding his unreliable methodology should be stricken and his expert testimony regarding such methodology should be precluded." Mylan's Br. at 6.

Pfizer responds that "[c]ontrary to the suggestion of Mylan's motion, Dr. Anderson did not conduct a *de novo* review of the stability of amlodipine salts. Rather, "he was

comparing what Dr. Platt[3] and his analysts recorded in his laboratory records to what Dr. Platt recorded in his summary memo . . . to determine if the summary memo in fact was a reasonable characterization of the individual laboratory results." Pfizer's Memo. at 3.

Mylan does not contest that Dr. Anderson is qualified as an expert in this matter[4] or, if Dr. Anderson's testimony is found to be admissible, that the testimony will not assist the trier of fact. Rather, Mylan strongly argues that Dr. Anderson's report and methodology do not meet the second requirement of Rule 702 because it is based on "unreliable information."

Pfizer responds that "[w]hat Mylan is complaining of does not relate to the scientific method used to evaluate stability, but Dr. Anderson's reporting and summary of the laboratory records. Such an objection does not relate to *Daubert*." The Court finds Pfizer's argument to be persuasive.

It appears that Mylan's challenge goes to the weight of the evidence rather than the admissibility of Dr. Anderson's testimony and analysis. During his deposition, Dr. Anderson admitted that "[t]here was quite a bit of missing data," and that he "would like more information." "The identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1345 (11th Cir. 2003); *see also In re TMI Litig.,* 193 F.3d 613, 692 (3d Cir. 1999)

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[3] Dr. Robin Platt, in Pfizer's Sandwich Analytical Chemistry Department, had the task of testing the amlodipine maleate drug product in bulk and in formulations for stability. Dr. Platt and his staff contemporaneously recorded their observations in Analytical Chemistry Data ("ACD") sheets, similar to laboratory notebooks.

[4] Dr. Anderson has a Bachelor of Arts in Chemistry, a Masters of Science, and a Ph.D. in Pharmaceutical Chemistry.

("'So long as the expert's testimony rests upon 'good grounds,' it should be tested by the adversary process - competing expert testimony and active cross-examination - rather than excluded from jurors['] scrutiny for fear that they will not grasp its complexities or satisfactory [sic] weigh its inadequacies.' " (*quoting Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir.1998)); *Wilmington v. J.I. Case Co.*, 793 F.2d 909, 920 (8th Cir. 1986) ("Virtually all the inadequacies in the expert's testimony urged here by [the defendant] were brought out forcefully at trial . . . . These matters go to the weight of the expert's testimony rather than to its admissibility.").

At trial, Mylan will have a full opportunity for "active cross-examination" of Dr. Anderson about the accuracy of his summary. Accordingly, the Court finds and rules that Mylan's motion will be denied.

Conclusion

For the foregoing reasons, the Court denies Pfizer's Motion in Limine to Preclude The Trial Testimony of Kevin Burgess Ph.D., and Mylan's Motion to Strike Dr. Anderson's Expert Report and Preclude His Testimony Regarding Unreliable Methodology.

An appropriate Order follows.

McVerry, J.

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	)	
Defendant and	)	
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ORDER OF COURT

AND NOW, this 17th day of November, 2006, in accordance with the foregoing Memorandum Opinion, it is hereby **ORDERED**, **ADJUDGED, AND DECREED** as follows:

1. The Motion in Limine to Preclude The Trial Testimony of Kevin Burgess Ph.D., filed by Pfizer Inc. is **DENIED**; and

2. The Motion in Limine to Strike Dr. Anderson's Expert Report and Preclude His Testimony Regarding Unreliable Methodology filed by Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. is **DENIED**.

BY THE COURT:

s/Terrence F. McVerry
United States District Court Judge

cc: All Counsel of Record